REMARKS/ARGUMENTS

Claims 1-26 are pending in the above-referenced application. No amendment has been made by the present Request for Reconsideration.

This is a Response to the Final Office Action dated March 30, 2009 wherein the Examiner rejected claims 1-26 under §103(a) as being unpatentable over Bialecki (US 6,652,486) in view of Tauschinski (US 4,387,879).

In view of the following remarks, reconsideration of the rejected claims and a notice of allowance are respectfully requested.

In rejecting claims 1-26, the examiner contends that Bialecki discloses essentially as claimed. However, the Examiner acknowledges that Bialecki does not disclose "wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after removal of the needle, and wherein the check valve remains in the catheter hub when the hollow needle is removed from the catheter hub in the catheter tube." (Final Office action, Page 3, emphasis in original).

To make up for the deficiencies, the Examiner alleges that "Tauschinski discloses (figures 1-4) a check valve (7) for use in the distal end of the catheter hub (1). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the catheter hub of Bialecki (Bialecki has space between the guard and the catheter tube as seen in figure 5) as disclosed by Tauschinski for providing a sealing valve to block fluid flow." (Final office action, page 3).

Although independent claim 10 was rejected, the examiner did not separately set forth the reasons other than merely repeating claim 10 within the text of the office action. (See, e.g., page 5).

Although independent claim 11 was rejected, the examiner did not separately set forth the reasons other than merely repeating claim 11 within the text of the office action. (See, e.g., page 5-6).

In view of the remarks that follow, reconsideration and a notice of allowance are respectfully requested.

PRINCIPLES OF LAW

Obviousness under 35 USC §103(a) is established as follows:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

In 2007, the KSR Supreme Court reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)). Furthermore, according to MPEP §2141, "Office personnel . . .[to perform the] critical role of fact finder when resolving the *Graham* inquiries. . . Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness."

Under 35 U.S.C. 132, a well articulated and reasoned Office Action is required so that an applicant may be properly notified of the reasons for the rejection of the claim so that he or she can then decide how best to proceed. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn,* 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "'[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational

underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. The "mere existence of differences between the prior art and an invention does not establish the invention's nonobviousness." *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976). MPEP §2141(III).

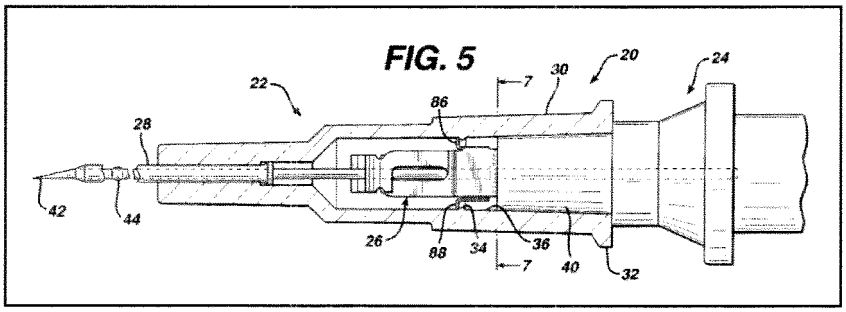
Once Office personnel have established the *Graham* factual findings and conclude that the claimed invention would have been obvious, the burden then shifts to the applicant to (A) show that the Office erred in these findings or (B) provide other evidence to show that the claimed subject matter would have been nonobvious.

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). MPEP §2143.02.

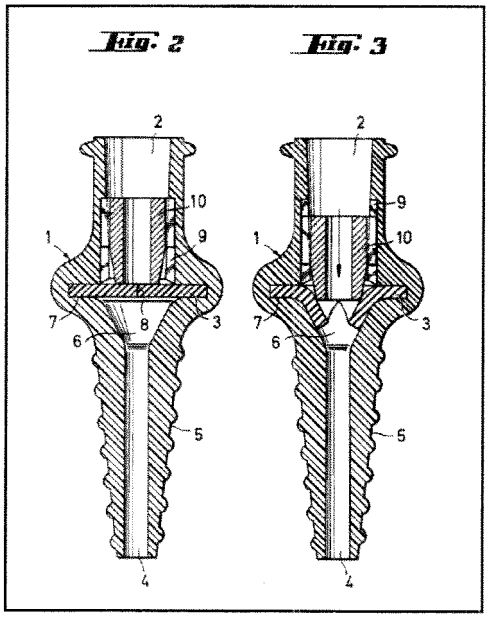
1) The Bialecki Reference

Bialecki discloses a catheter insertion device and ". . . in general, to intravenous (IV) catheters and, more particularly, to a safety IV catheter with a needle tip protector that will automatically cover the needle tip upon needle withdrawal." (Col. 1, lines 5-8).

As shown in FIG. 5 of the Bialecki reference reproduced to herein, the assembly 22 comprises a needle hub 24, a catheter hub 22, and a tip protector 26 located inside the cavity of the catheter hub 24 in a ready to use position. The tip protector 26 further comprises first and second tabs 86, 88 that are seated distal of an internal bump 34 (called rib) to retain the tip protector 26 within the catheter hub during retraction of the needle from the catheter hub following successful catheterization. (Refer to Col. 5:4-49 of the '486 Bialecki reference for a fuller explanation).



2) The Tauschinski Reference



Tauschinski relates to "a connector which is adapted to be connected to a plastic cannula or a vein catheter and comprises a tubular and/or conical portion that is adapted to be tightly joined to a parenteral solution supply needle and/or to a hose provided with a cone fitting." (Col. 1:7-12).

With reference to figures 2 and 3, Tauschinski discloses a connector body 1 comprising a cone section 5, and a conical portion 2 having a cylindrical member 10 slidably disposed therein. A disc 3 is positioned inside a peripheral groove 7 for sealing the cylindrical passage 4 from the conical portion 2.

The conical portion 2 is also provided with axial

guide grooves 9 for retaining the cylindrical member 10 (Col. 3, 23-25). According to Tauschinski, "[t]he member 10 has a central through bore and has a square rear end whereas its forward end portion is frustoconical." (Col. 3:27-29, emphasis added).

Figure 3 is a cross-sectional view of figure 2 in an open state. According to Tauschinski "member 10 is shown in a position to which it has been advanced by an oval fitting, not shown, of a supply hose. In that position the slit 8 is open because it has been expanded." (Col. 3:33-36).

Tauschinski did not disclose a gap, a space or proximally extending legs for the cylindrical member 10. The only space shown is the bore passing through the cylindrical member 10.

As summarized above from the office action, the rationale for combining Bialecki with Tauschinski is as follows:

> "it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the catheter hub of Bialecki (Bialecki has space between the guard and the catheter tube as seen in figure 5) as disclosed by Tauschinski for providing a seal sealing valve to block fluid flow." (Final office action, page 3).

ANALYSIS

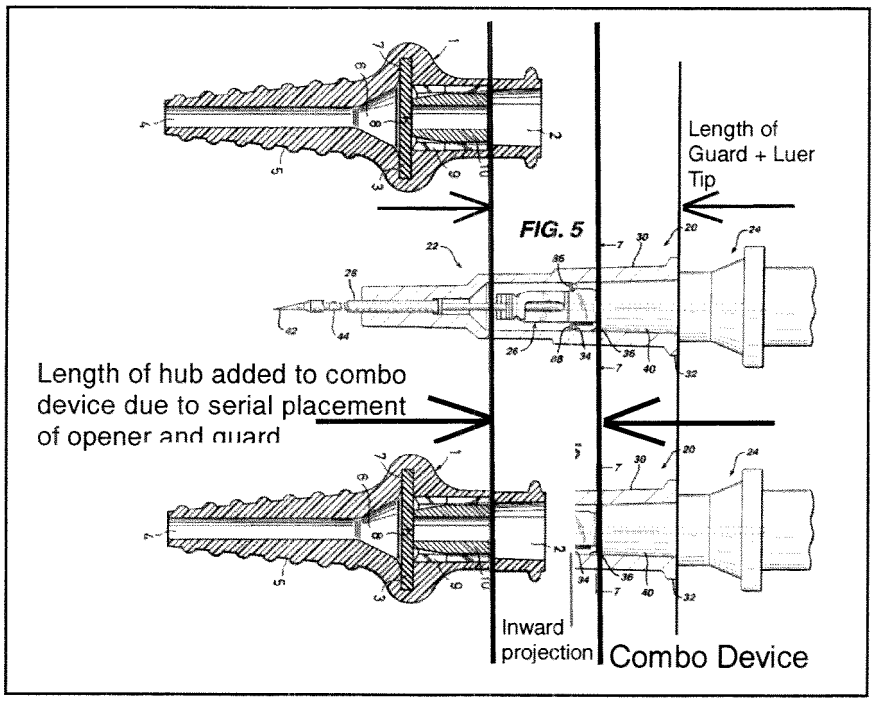
Compared to rejected independent claim 1, it is undisputed Bialecki, the primary reference, does not disclose:

1. "wherein a check valve is disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position;" and

2. "wherein the check valve remains in the catheter hub when the hollow needle is removed from the catheter hub and the catheter tube".

Thus, according to the examiner, the difference maybe bridged by combining the seal and seal opener disclosed by Tauschinski "for providing a seal sealing valve to block fluid flow".

Applicant submits that this modification produces a device that does not function with existing tools in the medical industry and therefore does not work. As such, the combination suffers from non-compatibility and therefore fail as a reference.



The suggested combination (called the "Combo Device") is reproduced to the left for discussion purposes.

To produce a device that teaches each and every element of claim 1, the connector body 1 of Tauschinski must be modified to accept a catheter tube, a tip protector, and a nose section of a needle hub.

This would require lengthening the connector body 1 of the Tauschinski device by the same length as the nose section 40 of the needle hub 24 and of the tip protector 26 of the Bialecki device. The combo device is reproduced as the third figure above. Note the relative size of the tip protector 26 to the catheter hub 22 of the Bialecki device (FIG. 5) and to the cylindrical member 10 of the Tauschinski device. The relative size of the tip protector 26 does not allow it to be placed inside the bore of the cylindrical member 10 since the various components are built to industry standards, which dictates how large the bore of the cylindrical member 10 can be. The problem is further compounded because the two arms of the tip protector 26 will need to spread radially outwardly in a ready to use position to mount over the needle. The Examiner has not shown nor did Bialecki disclose a way to produce a tip protector 26 that is capable of fitting inside the bore of the cylindrical member 10.

Furthermore, the tip protector 26 needs to engage the inward projection 34 on the interior surface of the catheter hub to operate properly or it will retract with the needle before the needle

tip is shielded. Therefore, even if it is placed inside the bore of the cylindrical member 10, it would not work properly due to the missing rib 34.

The first issue with the combo device is an unworkable conical portion 2 that extends too deep for "a oval fitting . . .of a supply hose". (Tauschinski, Col. 3:33-35). Thus, no existing supply hose is capable of exerting an axial force on the cylindrical member 10 to open the valve 3. Note that elements 32 of the Bialecki device is a Luer fitting. Therefore, only a standard male Luer fitting can be inserted into the hub to still ensure a leak-free seal - - because of a taper on taper fit provided by a Luer connector.

A second issue with the combo device is the inward projection 34 required to retain the tip protector 26 inside the hub in the ready to use position and during retraction of the needle. The inward projection 34 poses an obstacle for any would be oval fitting. Thus, even if a non-commercially available supply hose was used, the inward projection 34 would limit further advancement of the oval fitting from reaching the cylindrical member 10. Therefore, the cylindrical member 10 of the combo device cannot be actuated. As such, the combo device is a nonsensical device.

In view of the foregoing remarks, reconsideration and a notice of allowance of claim 1 are respectfully requested.

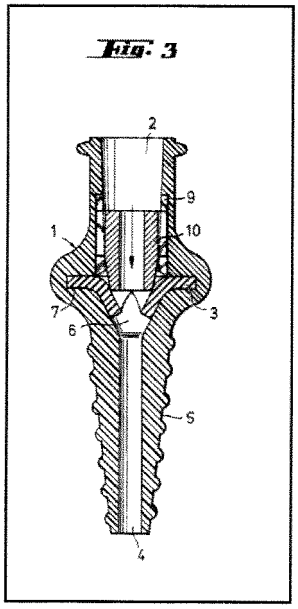
Because claims 2-9, 21, and 22 depend from claim 1, they too are allowable.

Furthermore, applicant submits that at the least claims 5 and 6 are separately patentable over the combo device. Claims 5 and 6 recite as follows:

> 5. The device according to claim 1, wherein the check valve comprises a valve disc, which has radial slits starting from a middle section of the valve disc, and a valve actuating element, which is displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element.
>
> 6. The device according to claim 5, wherein the valve actuating element is formed as a hollow cylinder with a truncated cone-shaped distal end section and comprising two proximally extending legs defining the hollow space for receiving the needle guard therebetween.

As previously discussed, Tauschinski discloses a cylindrical member 10 having a square rear end face for pushing by a nose section of a supply hose. (See, e.g., FIGs. 2 and 3 and Col. 3:25-29). There is no disclosure of an alternative configuration or a structure variation other than the square rear end face. As such, even if Bialecki and Tauschinski where erroneously combined, the combination does not disclose a hollow space for receiving the needle guard element as recited by claim 5. On page 4 of the office action, the examiner merely restated claim 5 in the reasons for rejection without specifying where the hollow space for receiving the needle guard element is shown in Tauschinski. Should the examiner again affirm the rejection, applicant respectfully requests the page, column, and lines of where the supposed limitation can be found. If the examiner's position is that the bore of the cylindrical member 10 provides the necessary hollow space, then the position is not realistic and has no fair basis. As stated above, the bore of the cylindrical member 10 is sized sufficiently small so that the cylindrical member 10 fits within the industry standard hub. For that reason, the Bialecki tip protector 26 simply cannot fit within the bore. Even if possible, the bore of the cylindrical member 10 does not incorporate a retaining mechanism for the tip protector 26 to work properly.

Reconsideration and notice thereof are respectfully requested.



Claim 6 modifies the hollow space of claim 5. In particular, the hollow space is defined as two proximally extending legs for receiving the needle guard therebetween. Applicant submits that there is no corresponding feature in Bialecki, Tauschinski, or the combination. As such, the combination failed to render claim 6 obvious. On page 4 of the office action, the examiner again merely restated claim 6 in the reasons for rejection but this time points to figure 3 for support.

Figure 3 of Tauschinski is again reproduced to the left. The examiner contends that cylinder 10 comprises "two proximally extending legs (figure 3 shows the hollow cone shaped actuating element) defining the hollow space for receiving the needle guard therebetween." (Office Action, page 4). Perhaps the examiner did not see the crosshatching and therefore assumed that cylinder 10 is actually two spaced apart legs,

when viewed in 2-D and not 3-D. Nonetheless, Tauschinski clearly explains that element 2 is a hollow conical portion, and element 10 is a cylindrical member. (Tauschinski, Col. 3:5 and Col. 3:25-27).

Reconsideration and notice thereof are respectfully requested.

The rejection of independent claim 10 is set forth on page 5 of the office action. In particular, the examiner repeats the reasons as supplied above for claims 1, 5, and 9.

Claim 10 recites:

> 10. A catheter insertion device comprising:
> a catheter tube attached to an end of a catheter hub, the catheter tube comprising a lumen and the catheter hub comprising an interior cavity;
> a needle defining a needle axis attached to an end of a needle hub, said needle projecting through the lumen of the catheter tube;
> a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub and in mechanical communication with a movable valve actuating element for opening the valve, and wherein the valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub; and
> a needle guard element comprising two needle guard arms crossing the needle axis of the needle positioned inside the catheter hub adjacent the valve in a ready position.

Applicant submits that claim 10 is patentable over Bialecki in view of Tauschinski for the reason that the two are not combinable. As discussed above, the combo device would produce a hub in which no present day Luer fitting could be used to actuate the cylindrical member 10 since the combination results in an extended bore. Another problem is with the inward rib 34 incorporated in the combo device for retaining the tip protector of Bialecki. This rib would prevent the Luer fitting from further insertion into the hub to actuate the cylindrical member 10, even if such a non-standard fitting was commercially available.

For at least the foregoing reasons, applicant submits that independent claim 10 is patentable. Reconsideration and a notice of allowance are respectfully requested.

Because claims 12-15 and 23 depend from claim 10, they too are allowable.

Furthermore, applicant submits that at least claim 15 is separately patentable over the combo device. Claim 15 recites as follows:

15. The catheter insertion device of claim 10, wherein the movable valve actuating element comprises two leg sections comprising a space therebetween for accommodating the needle guard.

As discussed above for dependent claims 5 and 6, Tauschinski discloses a cylindrical member 10 having a square rear end. As such, the combination does not disclose two leg sections comprising a space therebetween for accommodating the needle guard. Reconsideration and a notice of allowance are respectfully requested.

The rejection of independent claim 11 is set forth on pages 5-6 of the office action. In particular, the examiner repeats the reasons as supplied above for claims 1, 5, and 9.

Claim 11 recites:

11. A catheter insertion device comprising:
a catheter tube attached to an end of a catheter hub, the catheter tube comprising a lumen and the catheter hub comprising an interior cavity;
a needle defining a needle axis attached to an end of a needle hub, said needle projecting through the lumen of the catheter tube and comprising an engaging section near a needle tip;
a valve for regulating fluid flow positioned inside the interior cavity of the catheter hub, said valve comprising an opening and the needle projecting through the opening, and wherein the valve remains inside the interior cavity of the catheter hub when the needle is removed from the catheter tube and the catheter hub;
a needle guard element comprising an opening adapted to contact the engaging section of the needle positioned between the valve and the needle hub; and
wherein a valve actuating element is slidably displaced in the interior cavity of the catheter hub for opening the valve.

Applicant submits that independent claim 11 is patentable over Bialecki in view of Tauschinski for the reason that the two are not combinable. As discussed above, the combo device would produce a hub in which no present day Luer fitting could be used to actuate the cylindrical member 10 since the combination produces an extended bore. Another problem is with the inward rib 34 incorporated in the combo device for retaining the tip protector of Bialecki. This rib would prevent the Luer fitting from further insertion into the hub to actuate the cylindrical member 10, even if such a non-standard fitting was commercially available.

For at least the foregoing reasons, applicant submits that independent claim 11 is patentable. Reconsideration and a notice of allowance are respectfully requested.

Because claims 16-20, 25, and 26 depend from claim 11, they too are allowable.

Furthermore, applicant submits that at least claim 19 is separately patentable over the combo device. Claim 19 recites as follows:

> 19. The catheter insertion device of claim 11, wherein the valve actuating element comprises two leg sections comprising a space therebetween for accommodating the needle guard.

As discussed above for dependent claims 5 and 6, Tauschinski discloses a cylindrical member 10 having a square rear end. As such, the combination does not disclose two leg sections comprising a space there between for accommodating the needle guard. Reconsideration and a notice of allowance are respectfully requested.

In view of the foregoing remarks, the Application is thought to be in condition for allowance and early notice thereof is respectfully solicited.

Should the Examiner find it necessary to speak with Applicant's attorney; he is invited to contact the undersigned at the telephone number identified below.

Respectfully submitted,

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